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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,245	04/04/2001	Thyge Borup Hjorth	6184.200-US	2682

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[REDACTED] EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
1615	5

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/826,245	HJORTH ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Humera N Sheikh	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 July 2001.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-25 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> .	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

Acknowledgement is made of the Declaration and fees filed 07/09/01 and the IDS filed 07/23/01.

Claims 1-25 are pending. Claims 1-25 are rejected.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-6, 11-12, 19 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "low water content" in claims 4, 6, 11 and 12 is a relative term, which renders the claim indefinite. The term "(very) low water content" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term is indefinite because it does not clearly state the exact amount or percentage of water that the excipients contain.

The terms "low (water) vapor pressure" and "low oxygen pressure" in claims 5 and 19 are indefinite because it does not provide the exact extent or level of pressure required for the steps to be carried out in the process for the preparation.

The term "Tablettose" in claim 22 is indefinite because it is confusing and unclear as to whether one of ordinary skill in the art would recognize the term. Applicant is requested to provide some form of literature in which the Examiner is able to determine the patentability of the invention being made.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hulin (US Pat. No. 5,306,726) in view of Alvarez *et al.* (US Pat. No. 5,523,289).

Hulin teaches a pharmaceutical composition in the form of a tablet, powder or capsule comprising propionic acid derivatives or their pharmaceutically acceptable salts, in combination with a pharmaceutically acceptable carrier for use in the treatment of hypoglycemia and hypercholesterolemia associated with diabetes (see reference column 1, lines 15-47); (column 5, lines 7-40); (column 11, lines 41-68); (column 12, lines 1-25) and see examples. The composition is provided in a blood glucose lowering effective amount. Furthermore, additional components such as flavorants, sweeteners and excipients may be added to the composition. Hulin is deficient only in the sense that he does not explicitly disclose the use of an antioxidant in his formulation. It is the position of the Examiner that one of ordinary skill in the art would include an antioxidant

Art Unit: 1615

agent or preservative in their formulation to prevent oxidation or degradation of a compound composition. Such skill is also evident from the reference of Alvarez et al.

Alvarez et al. disclose a pharmaceutical composition comprising propionic acid derivatives and their pharmaceutically acceptable salts for oral administration wherein the tablet composition can comprise an antioxidant, such as tocopherol acetate (vitamin E) and the like. In addition, various excipients, fillers, disintegrants, lubricants, flavoring agents and coloring agents can also be formulated in the composition. The additives disclosed, for example, are microcrystalline cellulose, starch, pregelatinized starch, lactose, magnesium stearate, stearic acid, talc and colloidal silica (see entire reference, especially column 3, lines 45-60) and (see examples).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the formulation of Alvarez et al. with Hulin to obtain a stabilized pharmaceutical composition, comprising propionic acids and their acceptable salts in combination with antioxidants, with the expected result of a highly effective oral composition, enhanced by decreased oxidation for use in the treatment of diabetes.

Instant claims 20-25, provide for specified percentages. There is no criticality seen in the specified ratios of the additives and excipients. The prior art teaches the generic concept of including such ingredients (excipients, additives, fillers, lubricants) and it is deemed obvious that one of ordinary skill in the pharmaceutical art would determine suitable percentages through routine and conventional experimentation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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